Rejection under 35 U.S.C. §112, first paragraph

In the Office Action, claims 1-20 stand rejected under 35 U.S.C. §112, first paragraph, for allegedly lacking enablement. In particular, the Examiner specifically states that the application is enabling for production and use of recombinant constructs comprising the sarcotoxin1a gene and/or the hinge region from a chitinase gene and plant gene (*see*, Page 2, Item 3). As an initial matter, applicants note that claims 14 and 16-17 are directed to this aspect of the claimed invention and are included in the present rejection. The inclusion of these claims in the rejection is inconsistent with the Examiner's statements in the Office Action.

With regard to the remainder of the claims, the Examiner notes that specific teaching of the production of particular exemplified vectors (PSS and PSP) is provided and then alleges that specific exemplification of other vectors within the scope of the invention is required. The first paragraph of §112, however, has never been interpreted to require specific demonstration of particular embodiments of an invention. Indeed, the courts have specifically held that, while a large number of examples are desirable, they are not required by the statute, even in complex technologies. *In re Strahilevitz* 212 USPQ 561 (CCPA 1982). The dispositive issue is not the number of examples provided, but whether one of skill could make and use the claimed invention based on the disclosure provided.

It is well established that the Examiner bears the initial burden of providing evidence or reasoning why a pending claim does not meet the requirements of §112, first paragraph. A concise statement of the law is provided in *In re Marzocchi* 169 USPQ 367,369 (CCPA 1971):

> [a]s a matter of Patent Office Practice,... a specification disclosure which contains a teaching of the manner and process of making the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of §112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support... It is incumbent upon the Patent Office ... to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its

> own with acceptable evidence or reasoning which is inconsistent with the contested statement."
> *In re Marzocchi* 169 USPQ 367,369 (CCPA 1971) (emphasis in the original).

In the present case, no evidence or reasoning has been provided to explain why one of skill could not practice the claimed invention using the present specification and standard techniques. To properly support the rejection, the Examiner must show, for instance, that one of skill could not isolate identify other anti-bacterial genes that could be used to confer anti-fungal properties on plants. The Examiner does not address, for instance, the use of routine screens to identify other genes within the scope of the claims. In fact, as evidenced by the enclosed publication by Epple *et al.*, such genes have been identified.

Next the Examiner cites three publications which allegedly show that production of transgenic plants is unpredictable (*see*, page 4, first full paragraph). The primary point made by citation of these references is that additional empirical testing must be carried out to ensure, for instance, that promoters function properly (Kozel *et al. Plant Mol. Biol.* 32: 393-405 (1993)), that cosupression does not occur (Stam *et al. Ann. Bot.* 79:3-12 (1997)) or that the desired phenotype is obtained Smith *et al. Nature* 334:724-726 (1988). The assertion that this constitutes undue experimentation under the patent laws is simply incorrect. As the Federal Circuit has stated, "the key word is 'undue', not 'experimentation'" in determining whether pending claims are enabled. *In re Wands* 8 USPQ2d 1400 (Fed. Cir. 1988). Indeed, a considerable amount of experimentation is permissible if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. The Examiner has provided no reasoning or evidence to show that a technician in any plant molecular biology laboratory, could not screen and test transgenic plants made by the inventions of the invention for the properties outlined above. Finally, applicants note in light of the common use of plant molecular biological techniques and the routine production of transgenic plants, this basis for the rejection should not be maintained.

In the rejection, the Examiner cites the *in re Wands* factors to support the allegation that undue experimentation is required (paragraph bridging pages 3 and 4). The Office Action, however, simply lists the factors to be considered and does not apply these factors to the facts of the present case to determine if, in fact, undue experimentation is required. Since the burden is on the PTO to show a lack of enablement, Applicants respectfully submit that a proper showing has not been made. In the absence of a showing that routine, although laborious, could not be used to identify other genes within the scope of the claims and test transgenic plants for desired traits, the rejection of the pending claims is improper and should be withdrawn.

Rejection under 35 U.S.C. §112, second paragraph

Claims 2-19 stand rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite. These rejections are all obviated by the above-amended claims. All of the claims, except claim 19, have been amended as suggested by the Examiner. Applicants respectfully submit that all of the claim amendments were made to clarify the claim language and are fully supported by the specification. None of these amendments alter the scope of the pending claims. With regard to claim 19, the Examiner is directed to page 11, lines 18-25, where the term "expression vector" is defined to include vectors useful for transferring a expression cassette to a host cell. Thus, the claim is clear, when read in light of the specification. Withdrawal of the rejections is respectfully requested.

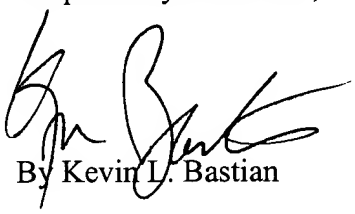
Rejections under 35 U.S.C. §§102(e) and 103

The rejection of claims 1 and 20 for allegedly being anticipated by Jaynes *et al.* and Broekert *et al.* is respectfully traversed. The present invention is based, at least in part, on the discovery that genes that encode anti-bacterial peptides can be used in plants to confer anti-fungal properties. The cited patents simply disclose "anti-microbial" or "biocidal" peptides, but teach nothing regarding whether these peptides would be useful in conferring resistance to fungal pathogens. The Examiner has identified nothing in the prior art that discloses or suggests this invention.

In addition, the rejected claims have been amended to specifically exclude the three peptides disclosed in the Jaynes *et al.* patent.

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (415) 576-0200.

Respectfully submitted,



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